

Managing End-Stage Heart Failure Today

Advances in medical therapy, mechanical devices, and the ability to successfully perform surgery in high-risk patients have revolutionized the management of patients with heart failure and are providing numerous alternatives to transplantation.

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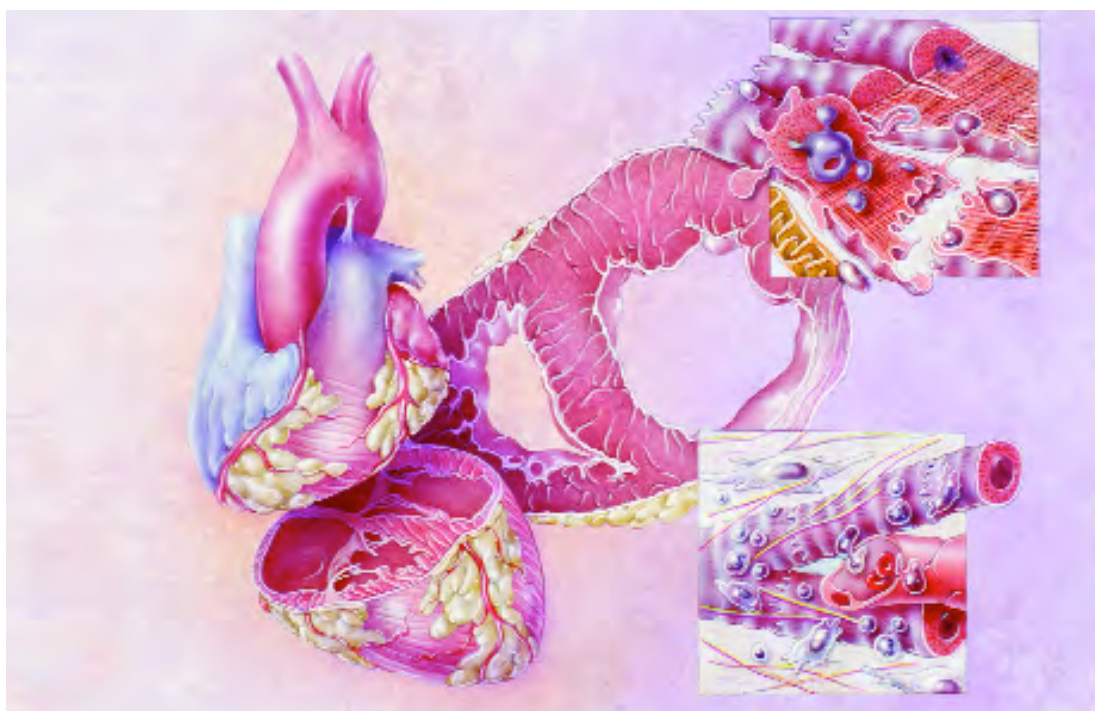
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Kevin A. Somerville, Photocast

Cellular changes in heart failure: cardiac muscle remodeling following infarction.

Pharmacological therapy is highly effective for the majority of patients with heart failure, even advanced disease. The right combinations of ACE inhibitors, beta-blockers, diuretics, and digoxin may prevent, attenuate, or even reverse heart failure. In symptomatic heart failure, biventricular pacing is now considered standard care for appropriate patients. "Today, standard medications and devices may be used in somewhat unique ways to manage even incredibly sick patients," states Deborah D. Ascheim, MD.

Patients with refractory disease or significantly compromised tolerance to medications may require

alternatives to medical therapy. Such patients, who until recently would have faced slim choices after medical therapy failure, may now benefit from a broad range of treatments.

At the Heart Failure Center of NewYork-Presbyterian Hospital/Columbia University Medical Center, a multidisciplinary team meets weekly to consider the range of options for each patient listed for transplantation. Patients who are doing reasonably well on oral therapy may remain on that course (designated status II according to UNOS classification). If oral therapy fails, inotropic infusions may be administered next (status IB).

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Adult Congenital Heart Disease

Birth of a new specialty

Congenital heart defects constitute the most common disease afflicting babies at birth. For years, little could be done to help children with severe defects, but thanks to advances in imaging technology, surgical procedures, pharmacology and molecular biology, an expanding number of such children now survive into adulthood. Some estimates hold that there may be as many as a half million adults with congenital heart disease in the U.S. — more adults than children with such defects.

The first adult patients with congenital heart disease typically continued to receive care from their pediatric cardiologists because these physicians were familiar with their patients' unique defects and surgical corrections. By age 30, however, they found the need to consult internists and adult cardiologists who could better address the health issues concerning adults. The paradox they faced was that these physicians were not trained or experienced in the care of patients with congenital heart defects. Today the unique problems of adult patients demand the expertise of physicians familiar with congenital heart anomalies, adult physiology, medical

issues in congenital heart disease, and late surgical problems arising from childhood surgical corrections.

"They may have been repaired as children, but they still need ongoing treatment by physicians experienced in the management of these defects," explains Rubin S. Cooper, MD. "In some cases, their conditions may be so serious that education, employment, and everyday functioning are affected; they require broad multidisciplinary care."

According to Welton Gersony, MD, the period between age 20 and age 30 is a crucial transition decade for patients with congenital heart disease. "Giving up their reliance on longstanding care by their pediatric cardiologist, and finding a qualified new cardiologist, can be a very difficult endeavor." Lack of proper serial evaluations and follow-up care can lead to the development of myocardial or pulmonary vascular complications that could have been prevented. Conversely, an inexperienced physician may "over test" or restrict patients with minor lesions, causing unnecessary patient anxiety.

Drs. Cooper and Gersony hope to make such transitions smoother and more successful through a new model of care. At New York-Presbyterian Hospital, they are now developing a joint clinical

program for congenital heart disease in which pediatric and adult specialists care for patients in partnership from childhood right through adulthood. In addition to medical and surgical care, they hope to offer specialized services including pregnancy care, rehabilitation, and job training. A generous grant has been given to achieve these ends by Joan and Michael Schneeweiss. "It is caring and compassionate individuals such as the Schneeweiss' who will make the difference for these patients over the years ahead," states Dr. Gersony.

If the growing population of patients with adult congenital heart disease is to receive excellent care, programs such as this will need to be developed nationwide. "Unfortunately, training of physicians who treat adults with congenital heart disease has been inadequate," Dr. Cooper states. "Very few institutions provide the necessary combination of pediatric and adult cardiology training." To address this need, New York-Presbyterian Hospital now offers a formal training program in both pediatric and adult cardiology, in the form of a five-year fellowship. "Its large patient volume and luminary medical and surgical faculty provide an outstanding academic and clinical environment for such training," according to Dr. Cooper. "Physicians



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who complete this training will be highly qualified to direct and coordinate the care of adults with congenital heart disease.”

Advances in Surgical Repair

Lessons from the past continue to impel changes in surgical practices, observes Ralph S. Mosca, MD. “When dealing with congenital heart disease, all treatment is more or less palliative,” he says. “We may create other problems in the process. Our hope is that the patients we treat now will need less treatment later.”

In the past, for example, repair of Tetralogy of Fallot was performed through a large opening in the ventricle. “Now we know this can lead to dilation and poor ventricular function,” says Dr. Mosca. Some of these patients are coming back for replacement of their pulmonary valves. “Today we do this repair through the right atrium, causing less injury to the ventricle, less pulmonary regurgitation, and fewer ventricular arrhythmias. It is likely that patients treated with this approach may avoid the need for pulmonary valve replacement in the future.”

Ross Procedure

When children and adults require aortic valve replacement, the Ross procedure is now the preferred method in many cases. “Until recently, patients with aortic valve disease received mechanical or homograft valve replacements, both of which require anticoagulation therapy. Neither alternative left patients free from problems, however, and a better solution was needed, particularly for children and for women who

wanted to become pregnant.” The Ross procedure, in which a pulmonary autograft is used to replace a deformed aortic valve, appeared to be a promising method. In children, the valve would grow with the child, avoiding the need for reoperation. In all patients the need for anticoagulation would be avoided.

Dr. Mosca recounts that in its early stages, the procedure (which is a more involved operation than the other valve replacement options) had a higher risk of early post-operative problems including leaking valves and need for re-operation. Now, however, improvements in technique have rendered it a very good option. In addition to avoiding the need for long-term anticoagulation, pulmonary valve deterioration occurs only very rarely.

The procedure remains complex, however, and successful outcomes depend on surgical expertise. Aortic regurgitation may result from improper placement of the pulmonary autograft. Harvesting the pulmonary artery poses some risk for damage to the septal coronary artery.

On the horizon: Insertion of pulmonary valve via percutaneous stent

Cardiac valves may be placed on a stent and inserted percutaneously rather than through open surgery, according to recent experience in Great Britain. After repairs performed through needle holes in the groin, patients return home the following day with virtually no recovery time. Results to date indicate successful functioning of the valves for at least 3½ years. “For adults whose pulmonary valves have been removed or are not developed, this is a very exciting development,” says William E. Hellenbrand, MD. Pending FDA approval, Dr. Hellenbrand will be one of the principal investigators of the first trial evaluating this technique in the US. European researchers are also evaluating percutaneous insertion of aortic valves in adult patients with aortic stenosis.

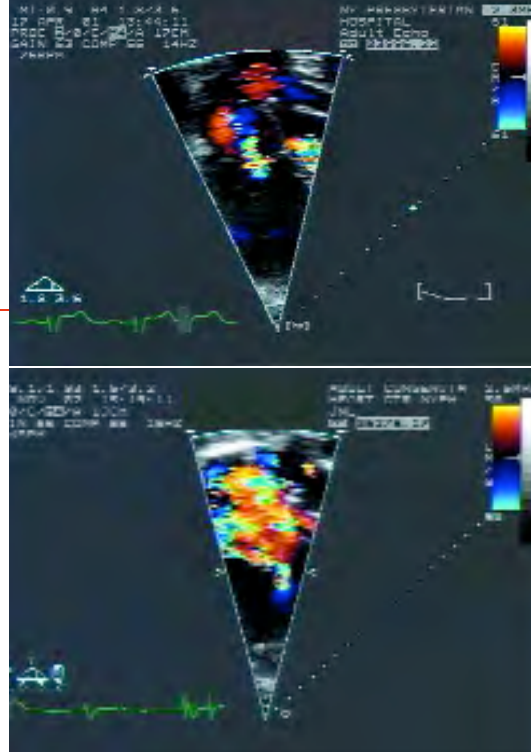


Figure 1. Mild tricuspid regurgitation is seen in this patient pre-pregnancy with d-TGA s/p Mustard repair.

Figure 2. Same patient in the 3rd trimester of pregnancy with severe tricuspid regurgitation.

Pregnancy in Women with Congenital Heart Disease

Patients with congenital heart disease are living longer, healthier lives due to remarkable advances in cardiac medicine and surgery. Women with cardiac anomalies who have mild disease or have had corrective operations are increasingly anxious to participate in one of the most common rites of adulthood: having a baby. Careful planning and monitoring by genetic counselors, perinatologists, obstetricians, and cardiologists now makes pregnancy a viable option for many such women.

According to Deborah R. Gersony, MD, women with common heart defects frequently become pregnant safely and deliver a newborn at term. These include patients with repaired atrial septal defect (ASD), repaired Tetralogy of Fallot, unrepaired small ASD or ventricular septal defect (VSD), bicuspid aortic valve without significant obstruction, and mild to moderate pulmonary stenosis. “Women with volume overload conditions such as atrial septal defect or valvular regurgitation generally tolerate pregnancy well. Those with significant valvular obstruction

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Lupus and Cardiovascular Disease

New research shows that chronic inflammation causes atherosclerotic cardiovascular disease independently of traditional risk factors in patients with Systemic Lupus Erythematosus (SLE). In the absence of clear biomarkers that can predict which lupus patients will suffer CVD, traditional risk factors warrant aggressive treatment.

Since the 1970s, patients with SLE have enjoyed increased survival rates thanks to therapeutic advances, only to die of cardiovascular disease at surprisingly high rates. The occurrence of myocardial

predict which of their patients would suffer myocardial infarction. Moreover, it has remained unclear whether treatments of SLE might be increasing or decreasing the risk of atherosclerotic cardiovascular disease.

"The increased presence of traditional risk factors for cardiovascular disease in some groups of SLE patients has long been recognized, but the high incidence of premature myocardial infarction in lupus patients suggested causes other than hypertension, hypercholesterolemia, obesity, or diabetes – possibly SLE itself, and/or its treatment," says Mary J. Roman, MD.

To investigate this question, a group of rheumatologists at the Hospital for Special Surgery, led by Jane E. Salmon, MD, collaborated with Dr. Roman and other cardiologists at Weill Cornell Medical College to conduct the first case-control study assessing the presence, magnitude, and causes of atherosclerosis in SLE.

Based on existing evidence, they suspected that chronic inflammation of the coronary vessels might be a critical factor. The team used ultrasonography to detect the presence of preclinical atherosclerotic disease in the carotid arteries, a strong correlate of cardiovascular events (usually myocardial infarction). Although patients and controls were comparable in their cardiovascular disease risk factors, the lupus patients had a 4.8-fold higher rate of carotid plaque. Patients with plaque were less likely to have multiple auto-antibodies, and were less likely to have used cyclophosphamide, prednisone and hydroxychloroquine than lupus patients without plaque.

"Our research showed absolutely that traditional risk factors cannot completely account for the prevalence of

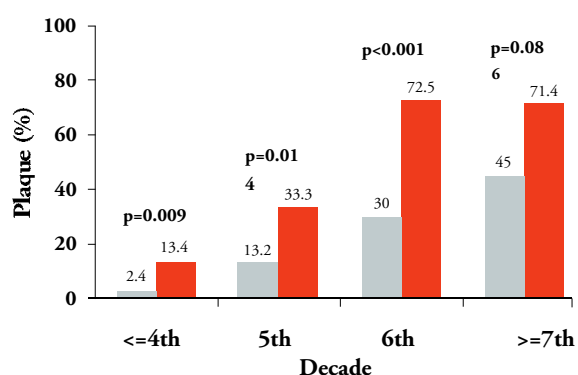
premature cardiovascular disease in patients with SLE," explains Dr. Salmon.

In their December 2003 article in the *New England Journal of Medicine*, Drs. Roman and Salmon reported that the high incidence of atherosclerosis among SLE patients, especially younger patients (under age 40) was not explained by the traditional risk factors (hypertension, hypercholesterolemia, obesity, diabetes). They found that atherosclerosis was associated with longer duration of disease, higher damage score, and a less aggressive use of immunosuppressant drugs.

"The prevailing view was that corticosteroid therapy contributed to cardiovascular disease in lupus patients, but our data show that treatment with prednisone was typically *less* in patients with atherosclerosis," says Dr. Salmon.

Their findings make sense in light of other research by Drs. Roman and Salmon on patients with rheumatoid arthritis (RA). Like the lupus population, patients with RA have a dramatic increase in prevalence of atherosclerosis (data not yet published). According to Drs. Salmon and Roman, chronic inflammation is very likely the cause in both diseases. "Systemic inflammatory diseases may have a similar pathway of atherosclerosis progression," says Dr. Roman. "It is likely that all of these patients should be treated more aggressively for cardiovascular risk factors."

Although traditional cardiovascular risk factors do not fully explain the prevalence of atherosclerosis in patients with SLE, Drs. Roman and Salmon believe that it is critically important to aggressively manage these factors nonetheless. "Unfortunately many rheumatologists do not rigorously monitor and treat the traditional risk factors of



Compared to healthy control subjects (gray bars), lupus patients (red bars) had a higher prevalence of atherosclerosis in every age group, especially the youngest patients (5.6-fold increase in lupus patients less than 40 years of age).

infarction among relatively young patients with lupus has long been recognized as both a great threat to patients and a great clinical challenge to prevent.

Despite agreement that SLE posed a high risk for cardiovascular disease, its causes have not been fully understood, and clinicians have been unable to



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Cardiac Surgery in the Ultra-Elderly

Ten years ago, performing cardiac surgery on patients in their 90s was unthinkable. Today it is becoming routine. Just how safe is this new practice? A Weill Cornell study finds surprisingly good results.

cardiovascular disease in lupus patients,” explains Dr. Salmon. The authors are now advocating a more aggressive approach to controlling the traditional risk factors of cardiovascular disease, particularly cholesterol and blood pressure, in their patients with SLE.

Ultimately, they seek to manage the systemic inflammation that characterizes SLE and other inflammatory conditions. *How to successfully treat chronic inflammation of blood vessels?* “This is the \$64,000 question,” says Dr. Roman. Lupus is traditionally treated during active flares with immunosuppressive therapy in order to control symptoms, and then reduced or stopped in order to minimize the side effects of these medications. The most effective way to achieve long-term control of inflammation remains unclear.

Drs. Roman and Salmon had hoped that their research would provide clear indication as to which disease markers might predict the development of CVD, but the cross-sectional results were not conclusive in this regard. Possible candidates include C-reactive protein, sICAM, and sCD40L, which are associated with an increased risk of cardiovascular events in the general population. Although these inflammatory mediators were elevated in lupus patients with atherosclerosis, there were no significant differences between patients with and without plaque, suggesting that these markers lose discriminatory power for predicting cardiovascular outcome in inflammatory diseases in which their levels are elevated, such as lupus. Longitudinal analysis, which may better define the relationship of these markers to the development and progression of atherosclerosis in lupus patients, is currently underway. ■

As the general population is living longer than ever before, physicians are caring for greater numbers of elderly patients with heart disease. Increasingly, they are asked to consider performing cardiac surgery in patients not just in their 70s, but in their 80s and even 90s.

How safe is it to operate on this patient population? Do the benefits of extending a patient’s life outweigh the risks of post-operative complication?

According to both research and case reports among the most experienced surgeons, elective cardiac surgery in select nonagenarians (individuals over 90) is remarkably safe overall. “Results are surprisingly good,” says Karl H. Krieger, MD. In particular, valve replacement surgery is especially successful in this population.

Prior to this year, research had demonstrated the safety of cardiac surgery on patients in their 70s. Now, Dr. Krieger and colleagues at Weill Cornell have completed the largest study to date of cardiac surgery in nonagenarians, or individuals over 90 (published in *Annals of Thoracic Surgery*, April 2003).

In their study, Dr. Krieger and colleagues analyzed the outcomes of 42 patients who underwent open-heart procedures during a ten-year period. With a median age of 91.4 years, the subjects underwent CABG, mitral or atrial valve replacement surgery, aortic aneurysm surgery, or combinations of the above procedures.

The post-operative survival rate was 95% at day 30 and 81% at 2½ years. The



Brad Hies

At age 87, Walter Glaser underwent surgery to repair the leaking mitral valve responsible for his heart failure. Since his successful operation by Dr. Krieger, he has resumed his busy schedule and enjoys a very good quality of life.

only deaths occurred in patients undergoing CABG, with emergency surgery increasing the risk of death seven times the risk associated with elective surgery. Pre-operative comorbidities for the study group included hypertension (67%), congestive heart failure (52%), history of arrhythmias (38%), prior myocardial infarction (31%), and renal insufficiency (21%).

Despite the encouraging survival rates, post-operative morbidity did remain significant, with two thirds of the subjects experiencing at least one complication. New arrhythmias developed in 31% of those studied (most medically managed); other complications included respiratory failure and pneumonia, infections, and emboli. Overall, length of stay in the hospital was approximately double that of younger patients.

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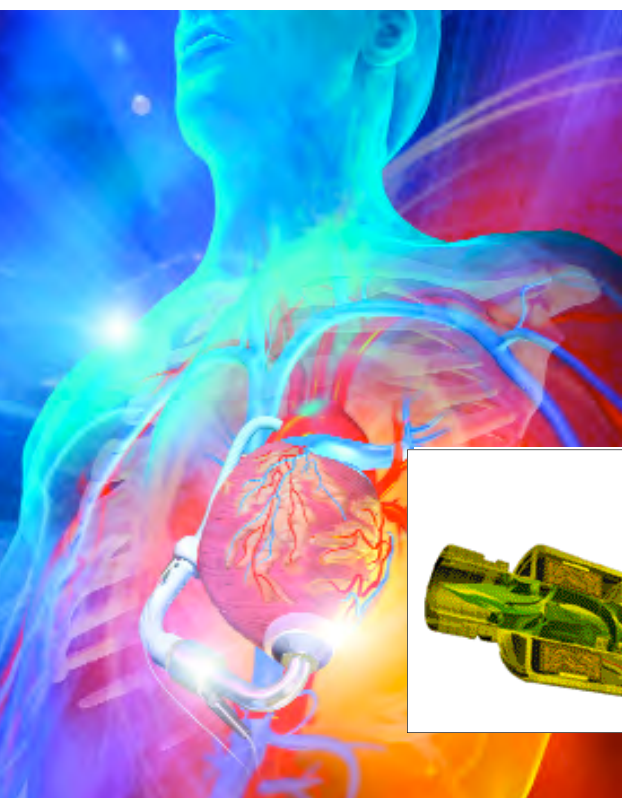


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Managing End-Stage Heart Failure Today

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Critically ill patients in the ICU (status IA) may be considered for device implantation in order to increase the likelihood of survival until transplantation. If the disease is too advanced to consider any of these options, intravenous medications may be administered at home for palliative end-of-life care.



DeBakey® LVAD

Image courtesy of MicroMed Technology, Inc.



Mechanical Devices: LVADS and Biventricular Pacing

VADs as Bridge to TX

The majority of ventricular assist devices implanted at NewYork-Presbyterian/Columbia are done on an urgent basis, according to Yoshifumi Naka, MD, PhD. In a study of this center's experience, survival among emergency VAD recipients compares quite favorably to

that among non-urgent VAD recipients. Seventy percent of those who receive an assist device as an emergency bridge to transplantation survive to transplantation, compared to 83% who undergo elective surgery.

Nevertheless, "determining whether to implant a left ventricular assist device (LVAD) or wait for a transplant can be a very difficult decision," according to Dr. Naka. Asks Dr. Ascheim, "At what point is really sick – sick enough to receive a device, while taking into account that the patient could receive a heart transplant any day instead?"

VAD as Destination Therapy

For patients who are not transplant candidates due to age or comorbidity, LVAD as destination therapy may also be considered. Despite FDA and CMS

approval, however, this is still relatively new territory and problems remain, particularly a high infection rate associated with the percutaneous drive line. Implementation of infection control protocols has substantially reduced the infection rate associated with the

devices, but physicians at NewYork-Presbyterian are working to reduce it even further.

Having spearheaded the REMATCH trial, the NewYork-Presbyterian/Columbia surgical team is continuing its efforts to improve the safety and success of LVADs. They are now testing two new, smaller devices based on entirely different technology than the devices tested in REMATCH. In a departure from the earlier models, Micromed's DeBakey® LVAD and Thoratec's Heartmate™ II both use a continuous flow rotor to pump blood through the

body. They also employ smaller tubing through the skin, which the physicians hope will reduce the rate of infection.

Biventricular Pacing

Physicians at NewYork-Presbyterian/Weill Cornell are increasingly using cardiac resynchronization therapy (CRT) to treat patients with symptomatic congestive heart failure who have prolonged QRS duration as identified by EKG. According to Maryjane A. Farr, Director of the Heart Failure Program at NewYork-Presbyterian/Weill Cornell, "The institution has long been a major referral center for this therapy, and has participated in major clinical trials including CONTAK CD, Companion, and PAVE." These studies have demonstrated clear benefits in symptoms, quality of life, and mortality, and CRT has also been shown to have favorable effects in reversing ventricular remodeling. The Companion trial, terminated early because of clear survival benefits to patients with heart failure, found a 20% reduction in mortality with cardiac resynchronization therapy, with or without defibrillation. In patients with combined devices, mortality was reduced by 40%.

Evaluation for Transplantation

Despite its great strides in recent years, cardiac transplantation remains a last resort for the very few patients sick enough to have failed all the other options, and lucky enough to receive a donor organ. As physicians continue to gain experience with medications, LVADs and other devices, these alternatives are available to increasing numbers of patients with end-stage disease. Given the scarcity of donor organs (average 2200 per year nationwide), this is very good news to the thousands of patients with end-stage

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heart failure who would likely not qualify as recipients.

As a result of the ongoing changes in treatment protocols, “the evaluation criteria for transplantation are in a constant state of revision,” according to Donna M. Mancini, MD.

Today, eligibility criteria for cardiac transplantation at NewYork-Presbyterian/Columbia include patients with:

- refractory cardiogenic shock
- documented dependence on intravenous

inotropic support to maintain adequate organ perfusion

- class IIIB/IV congestive heart failure with Peak VO_2 less than 14 mL per kg per minute
- severe symptoms of ischemia that consistently limit routine activity, and are not amenable to CABG or percutaneous coronary intervention
- recurrent symptomatic ventricular arrhythmias refractory to all therapeutic modalities.

STICH Trial Investigates Revascularization in Patients with Congestive Heart Failure

Large trials in the 1970s examined whether surgery or medical therapy was superior for people with obstructive multi-vessel coronary disease. Based on that data, it has been virtually taken for granted that patients with congestive heart failure and obstructive multi-vessel coronary disease should be bypassed if possible, and that they will do better with surgery.

Because most of the study subjects had normal heart muscle function, however, this early data did not adequately represent patients with weakened heart muscle. Patients with ejection fraction below 35% were excluded from most of these studies altogether. Moreover, they did not evaluate the effects of lipid-lowering drugs, aspirin, ACE inhibitors or beta blockers, all of which offer huge survival benefits to such patients. Deborah Ascheim, MD and colleagues are now seriously questioning whether many patients with ischemic cardiomyopathy should be revascularized or not.

“A subgroup of people with left main coronary artery stenosis or refractory angina truly do need mechanical reperfusion. But in light of the success we can achieve with medical therapy, it’s no longer clear whether we should bypass the majority of patients that we do,” says Dr. Ascheim. “We know our surgeons can get such patients through the surgery, but are they really improving their long-term outcome? Or will they soon be needing a transplant?”

The multicenter, NHLBI-funded Surgical Treatment for Ischemic Heart Failure (STICH) Trial is designed to answer these questions in light of the recent advances in medical therapy. The randomized trial will evaluate the outcomes of CABG versus medical therapy in patients with cardiomyopathy from NYHA class I-IV; one arm of the study will compare CABG to medical therapy in patients with ischemic cardiomyopathy. A second will compare CABG and surgical ventricular restoration therapy. A third will compare CABG, medical therapy and surgical restoration.



Coronary artery bypass grafting on a patient with ischemic cardiomyopathy.

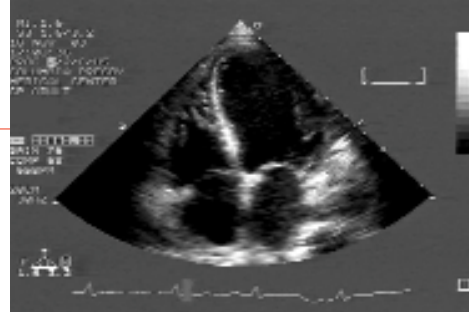


Figure 1: Echocardiogram of a patient with congestive heart failure

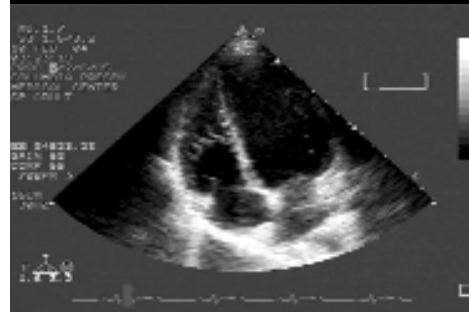


Figure 2: Normal heart

Exclusion criteria include:

- significant comorbid illness which limits post-transplant survival
- age greater than 72 years
- active or recent malignancy
- severe pulmonary hypertension as evidenced by a fixed pulmonary vascular resistance of greater than 6 Wood units
- significant chronic, irreversible, functional impairment of other vital organs including
 - renal:** creatinine > 2.5, or creatinine clearance < 25 ml/min
 - liver:** bilirubin > 2.5; ALT/AST > 2 times normal
 - lungs:** moderate to severe chronic bronchitis, chronic obstructive lung disease
 - blood:** significant coagulation abnormalities, bleeding diathesis.
- hypertension that requires multi-drug therapy
- active infection
- severe obesity (BMI > 35), or cachexia (BMI < 20)
- drug, tobacco or alcohol abuse within the previous six months
- active mental illness or psychosocial instability.

“We need to select those patients for transplantation who will have the best chance of surviving in the long term,” says Dr. Mancini. First and foremost, the team makes sure that medical therapy has been maximized. They will generally consider transplantation for patients who have failed



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maximum medical therapy and who have severely reduced ejection fraction, and who require intravenous or mechanical support.

At the same time, however, NewYork-Presbyterian/Columbia's criteria have broadened considerably such that many patients not previously considered for transplantation are now eligible. This group includes patients with diabetes who take insulin and may have minor organ damage; patients with HIV; and patients with amyloidosis. In addition, "although transplantation has previously been reserved for younger patients, we will now transplant patients into their early 70s," she says. Moreover, the team now performs high-risk transplantation, matching higher risk patients (previously considered ineligible due to age or illness) with organs that would normally be excluded from transplantation due to age, functional status, or health condition of the donor. With this new protocol, the team is able to save the lives of about 15 patients per year who otherwise would not qualify for transplantation. ■



Pediatric Heart Failure & Cardiomyopathy Center Opens

A new, comprehensive center for the prevention and treatment of pediatric heart failure is now open at the Children's Hospital of NewYork-Presbyterian. This multidisciplinary center evaluates and treats children with all types of cardiomyopathy and heart failure, and has a particular strength in the treatment of metabolic and genetic syndromes associated with cardiomyopathy. Consultations are available for both inpatients and outpatients.

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Left Ventricular Assist Devices (LVAD) as Destination Therapy

CMS coverage gives hope for thousands with terminal heart failure.

In November 2003, the Centers for Medicare and Medicaid Services (CMS) approved national reimbursement for left ventricular assist devices (LVADs) as destination therapy for acute heart failure patients who are ineligible for transplantation. The FDA approved LVAD as destination therapy a year earlier. Since most patients are Medicare age, however, approval by the CMS is having major and immediate ramifications. "With Medicare coverage, we are beginning to treat patients who were otherwise hopeless," states Eric A. Rose, MD.



HeartMate™ II LVAD

Reprinted with permission from Thoratec Corporation.

"LVADs will now be available to the sickest of the sick across the country, affording them greatly improved lives away from the hospital," he says. Dr. Rose was principal investigator of the REMATCH trial, the results of which prompted the FDA's November 2002 approval.

The three-year multicenter REMATCH trial demonstrated that the LVAD can significantly extend the length of life and improve quality of life among this patient group. Patients who received LVADs had a one-year survival rate of greater than 50%, as compared to a 25% survival rate with medical therapy.

Since publication of that data in November 2001, the results have improved even further, according to Dr. Rose. While the two-year survival rate was zero in the early stages of the trial (1996 – 1998), the most recent cohort (from 2000 on) has a 37% survival rate at two years.

Numerous developments account for this marked improvement, he explains. "We've made modifications in the device itself, and we have learned how to better manage infection, nutrition, and treatment of drive lines." Valves within the HeartMate™ LVAD have been altered since the trial began, as have the computer algorithms that run the device.

Dr. Rose foresees that a new generation of LVADs will in time surpass those tested in REMATCH. "While LVADs are clearly better than medical alternatives in regard to quality of life and survival, there is certainly room for improvement. We are already seeing improvements being made."

Selection criteria for LVAD as destination therapy include patients who:

- are not transplant eligible
- do not have end-stage kidney disease, liver disease, or diabetes
- have not had two open heart procedures
- are younger than 80 years of age
- have had chronic heart failure and are on medication for 60 of the last 90 days
- are expected to live two years or less without the device.

Patients receiving such devices are enrolled in a mandatory registry to track their outcomes. ■



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Cardiac Surgery in the Ultra-Elderly

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Nevertheless, Dr. Krieger operates successfully on patients over 80 every week. While he would not have considered surgery on patients this age just ten years ago, Dr. Krieger is acutely aware of the need to serve this dramatically growing population. By 2050 the number of individuals over 90 in the U.S. is projected to be 8.8 million, compared to 1.6 million today. While elderly patients in other countries may not be able to access costly surgical procedures, most patients in the U.S. can receive coverage through Medicare.

Improvements in surgical techniques relating to cardiopulmonary bypass, myocardial protection, and peri-operative care have played an important role in the success of surgery on ultra-elderly patients, according to Dr. Krieger. But maintaining rigorous patient selection criteria is crucial, he states. Dr. Krieger carefully evaluates patients' neurological function, kidney function, and ambulatory status. In addition, he says, "Family support is critical. Perhaps most importantly, however, is the patient's own motivation. Patients have to have a reason for wanting to continue to live." ■

Adult Congenital Heart Disease

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tolerate pregnancy less well and may need therapeutic interventions to compensate for the increased hemodynamic demands of pregnancy." Compared to women without congenital heart defects, many women with more severe congenital heart disease face an increased risk of miscarriage and of having a child with a congenital heart defect. The outcome of pregnancy and proper management of these patients has not been well established.

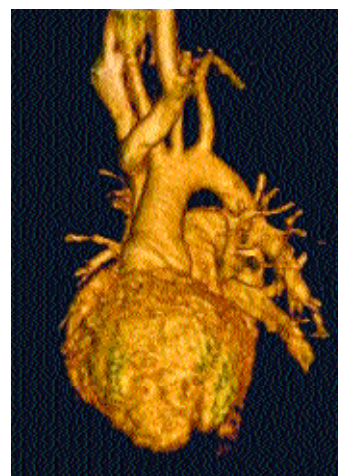
Dr. Gersony is now working to determine the cardiac risks during pregnancy in patients with the most complex lesion, systemic right or single ventricle (in which the right ventricle, rather than the left, is attached to the aorta). Ventricular dysfunction in such patients is associated with an increased risk of cardiovascular events including heart failure, even in those who appear to have no symptoms. Because the hemodynamic effects of pregnancy may further increase the risk of right ventricular dysfunction and systemic atrioventricular valve regurgitation, pregnancy is usually thought to be contraindicated. However anecdotal data suggest that if patients are clinically well, they may in fact tolerate pregnancy safely. Since no large series of patients have yet been investigated, Dr. Gersony intends to discover which patients with this condition may safely become pregnant, and which are at high risk of arrhythmia and heart failure.

With funding from the Heritage Affiliate of the American Heart Association, Dr. Gersony is leading a prospective, multi-site, case-control study evaluating the changes in ventricular function that occur during pregnancy. The study will use echocardiography to evaluate the serial effects on ventricular and atrioventricular valve function in subjects with systemic right or single ventricle compared to a case-control population. In addition, it will evaluate changes in diastolic function, fetal uterine blood flow, maternal cardiac, neonatal and obstetrical risk between subjects and controls.

Eligible subjects include women in their first trimester of pregnancy with:

- D-Transposition of the great vessels and Mustard or Senning repair;
- congenitally corrected L-transposition; or
- palliated or non-palliated single ventricle anatomy.

It is expected that the results of this study will help to develop guidelines for physicians who advise patients with these heart defects. ■



Adult patient with D-transposition of the great vessels after Mustard repair.

E-Valve: Percutaneous Approach to Mitral Valve (MV) Surgery

NewYork-Presbyterian Hospital/Columbia is one of seven medical centers nationally to participate in a Phase I clinical trial of the *E-valve* MV Repair System, which provides a percutaneous alternative to the open surgical approaches. The *E-valve* system entails placement of a clip on the MV, approximating the anterior and posterior leaflets, in the catheterization laboratory under fluoroscopic and transesophageal echo guidance. All candidates for surgical MV repair should be considered. Early results have demonstrated successful repair of the mitral valve, with no significant complications in any patient. For more information, contact Dr. Hal Wasserman (hsw1@columbia.edu) or Dr. Allan Schwartz (as20@columbia.edu).

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NewYork-Presbyterian Heart is comprised of physicians of Columbia University College of Physicians & Surgeons and Weill Medical College of Cornell University representing medical and surgical disciplines working together with other health professionals in a collaborative process.

Faculty Highlights



Mary J. Roman, MD is Professor of Medicine, Weill Medical College of Cornell University and Attending Physician, NewYork-Presbyterian Hospital/Weill Cornell Medical Center.

Motivated by a deep desire to improve the lives of her patients, Mary J. Roman, MD focuses her talents on areas of great potential that have not yet received wide study. Current studies include causes of premature atherosclerosis in patients with lupus and rheumatoid arthritis; pregnancy risks in the Marfan syndrome; and impact of intensive medical treatment in American Indians with diabetes. In her spare time she enjoys swimming, opera, and collecting photography.

After earning her medical degree from Columbia University College of Physicians & Surgeons, Dr. Roman completed postgraduate training at Harlem Hospital, NY, and served as Cardiology Fellow at the New York Hospital and Cornell University Medical College. Dr. Roman's recent publications include "Comparison of cardiac structure and function in American Indians with and without the metabolic syndrome (the Strong Heart Study)." *American Journal of Cardiology* 2004;93(1):40-4, and "Prevalence and Correlates of Accelerated Atherosclerosis in Systemic Lupus Erythematosus" *New England Journal of Medicine* 2003; 349:2399-2406.

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Yoshifumi Naka, MD, PhD is Herbert Irving Assistant Professor of Surgery, Columbia University College of Physicians & Surgeons, and Director, Cardiac Transplantation and Mechanical Circulatory Support Program, NewYork-Presbyterian Hospital/Columbia University Medical Center.

Yoshifumi Naka, MD, PhD earned his medical and post-doctoral degrees at the Osaka University Medical School, Japan. Upon his arrival at Columbia University in 1993 he began his specialization in cardiac and pulmonary transplantation, both in clinical practice and research efforts. Dr. Naka is currently principal investigator of "Vein Graft Preservation: Thrombosis & Neointimal Disease," a four-year study funded by the NIH, and the one-year study entitled "Recovery of the left ventricle during left ventricular assist device support," funded by the Foundation for Advancement in Cardiothoracic Surgery. Under his leadership, the Cardiac Transplantation and Mechanical Circulatory Support Program has earned international recognition for its contributions in developing and testing new cardiac devices and in training cardiothoracic surgeons.

Recent publications include "Bridging to Transplant With the Heartmate™ Left Ventricular Assist Device: The Columbia Presbyterian Twelve-Year Experience," *Journal of Thoracic Cardiovascular Surgery* (in press).

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